

The path towards better security of supply in Europe



Teva is a strategic partner of European healthcare systems, improving lives of around 200 million people worldwide.

Across Europe:



Teva employed **19,236** people



Teva operated **31** manufacturing and research and development facilities

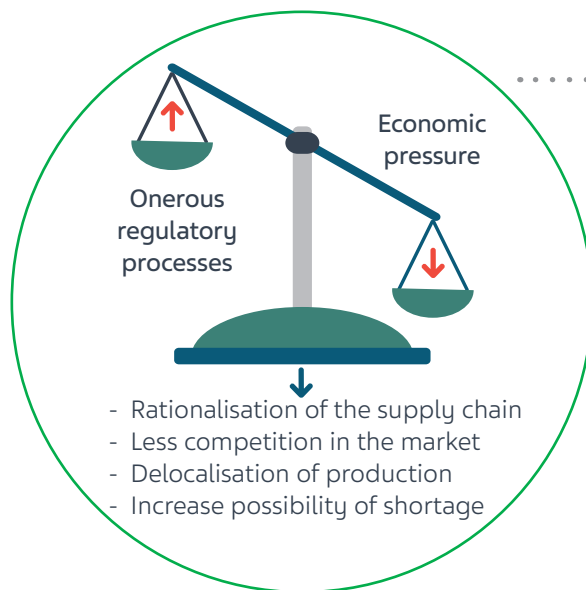
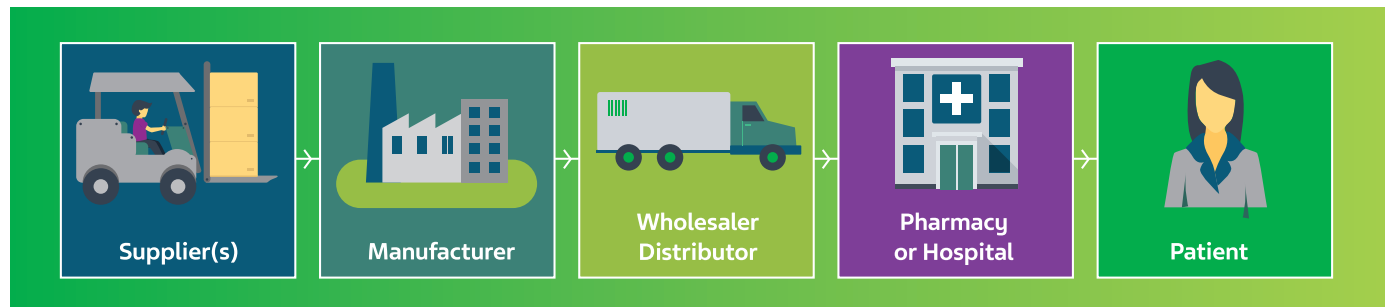


Teva saved healthcare systems more than **€ 7.6B**



There are **4** main Teva API sites in Italy, Croatia, Czech Republic & Hungary

The pharmaceutical supply chain is global and complex. Tackling all the bottlenecks encountered throughout the chain together with all concerned actors is crucial.



..... The commoditisation of products and current pharmaceutical policy landscape are challenging the sustainability of the pharmaceutical supply chain as a whole and challenge the resilience, autonomy and diversity of the pharmaceutical supply, leading to rationalisation of the supply.

..... Root causes and solutions

Security of supply must be ensured by addressing the root causes of medicines shortage and implementing sustainable economic, regulatory and industrial policies.



Regulatory

Regulatory time lag, National requirements, increase costs and burden of new regulation

Manufacturing

Manufacturing capacity, Natural disasters, Manufacturing lag times, GMP issues, Surges in demand, API and excipient supply

Supply chain

Supply quotas and parallel export, inefficient logistic coordination

Economic

Market conditions, Pricing mechanisms, Tender practices, Cost-containment measures, Commercial Withdrawals

Solutions

- Single pan-European monitoring and reporting system
- Regulatory flexibility
- Use of digitalisation and telematics tools

Solutions

- Incentives to reward security of supply investments
- A clear and ambitious industrial policy strategy

Solutions

- monitoring of inventory development
- informing pharma companies if competitors communicate out of stock risks
- 2-way-communication and True partnership between Healthcare Authorities and industry

Solutions

- Predictable pricing and reimbursement policies
- "stability" pacts
- Better uptake of generic and biosimilar medicines
- Sustainable procurement and new pricing models

Lessons learned from the Covid-19 pandemic

- Manufacturers had contingency plans in place avoiding any major disruption for critical products;
- National hoarding and stockpiling undermines industry's ability to deliver equitable supply in all markets;
- EU and national coordination to ensure equitable supply of medicines is important;
- Avoiding shortages requires bilateral dialogue, demand visibility and close cooperation between governments/regulators and actors.



Respecting the integrity of the single market is central to address security of supply while securing equitable access to medicines across Europe: A Pan European coordination and dialogue, reflecting the way the supply chain is organised is key as opposed to individual and uncoordinated measures at national level.



- A focused, action oriented High Level Pharmaceutical Forum led by the European Commission and involving authorities and all concerned stakeholders of the healthcare supply chain, ensuring Europe coordination and Solidarity
- Ensure Sustainable Market Conditions : Rewarding supply is crucial
- Ensure implementation of tenders MEAT (Most Economically Advantageous Tender) criteria beyond lowest price through EU Guidance
- An EU modern and digitalised regulatory framework (e.g. multipacks and eLeaflet as the norm)
- A single harmonised pan European definitions of medicines shortage and critical list of products
- Secure European investments in manufacturing & supply through sustainable economic, regulatory and industrial policies;
- A single pan European harmonised reporting and notification system on a pan European critical list of products



- Unharmonised national definitions and reporting requirements
- National artificial stockpiling or hoarding which disrupt European patients equitable and affordable access to the medicines
- Unproportioned and unnecessary penalties, creating further unsustainability and increasing the possibility of medicines shortage

What Teva is doing

Tackling and preventing shortages by ensuring security of supply is a priority for Teva. As such, Teva is committed to investigate, identify and address the root causes which impact our ability to supply medicines to the best extent we can. To that aim we have deployed tools and processes to minimise supply disruption. We are continuously looking at our performances to better understand, detect, report, communicate, and act against shortages. We are also collaborating with authorities to best address external barriers which impact our ability to best mitigate or prevent the root causes of shortages.



Organisation

- Teva has already a robust organisation to monitor and address supply issues. Teva has notably set up a multi-functional shortages Task Force aiming at:
- Ensuring full compliance with EU guidelines for detection, notification, and communication of drug shortages;
 - Providing agreed advice to improve internal processes to avoid drug shortages such as an SOP describing Drug Shortage Management



Regulatory

Teva is already engaged in reducing drug shortages by a variety of regulatory mitigating actions. The interactions with authorities can be a deciding factor and the response time and requirements can have an impact on the availability of alternative products (e.g. Importation; Repackaging, Alternative Dossier Registration), hence the need for permanent regulatory flexibilities and optimisation



Manufacturing

Teva performs risk assessment and manufacturing optimisation initiatives for critical medicines (e.g. site transfers)



Supply chain

Teva monitors market dynamics (e.g. use of artificial intelligence), assesses and adapts demand forecast in relation to priority medicines (e.g. prioritisation of shipping)